

REMARKS

Entry of the foregoing amendment is requested. Claims 88-104 will be pending.

Applicants would first like to address the issue of precisely what is being claimed, as per the rejection under 35 U.S.C. § 112.

First, with reference to claims 88, 89, 91, 92, and 94, which may be the most problematic claims, first note that claims 88 and 91 are drafted in “consisting essentially of” language, as compared to claims 89, 92 and 94, which use “consisting of.” This, *de facto*, creates a difference in scope.

Further, claims 88 and 89 require that the glycosylated molecules claimed have average values. Hence, undivided molecules within the composition may have more, or less than the recited values, as long as the average value is as recited. Claim 94, in contrast, requires that the molecules all have the recited values. All molecules must have the same values.

Claims like claim 93 are believed to address the issue raised previously against claims 45 and 48.

Applicants now turn to the prior art rejections. The Examiner has deemed all claims as having been anticipated by Watson, Takeuchi, Blumen, Akamatsu, Nimtz, or Strickland. In each case (with the exception of Nimtz), the Examiner has taken the position that production of EPO in CHO cells inherently produces what is claimed.

Review of Nimtz, however, shows that this is not the case. In the Nimtz abstract, the authors report that at most, 26.8% of N-acetyl-lactosamine repeats were found. To quote Nimtz:

“Many (82.7%) were found to be tetraantennary N-acetyl-lactosamine-type (22.8% with one, 3.6% with two and 0.4% with three N-acetyl-lactosamine repeats).”

Now, note the language of, e.g., claim 88:

“wherein the proportion of carbohydrate chains with N-acetyl-lactosamine repeats relative to the total number of N-linked carbohydrate chains is at least 30%”


For anticipation to lie, each and every element of a claim must be taught. Clearly, Nimtz does not teach this, and evidences that the “inherency” alleged by the Examiner does not exist.

Inherency only applies when all features of a claim result inevitably from the prior art. One cannot tell from any of Watson, Takeuchi, Blumen, Akamatsu, or Strickland what percentage of the EPO molecules contain N-acetyllactosamine. Whereas some references, e.g., Blumen and Strickland discuss sialic acid content, such is not N-acetyllactosamine content, and one cannot “bootstrap” from the other.

Adding EPA 267 678 and Hokke does not change this. The Examiner alleges that routine optimization could produce the claimed invention, but does not show this. As such, the rejection cannot be sustained.

Allowance is believed proper, and is urged.

Respectfully submitted,

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